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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,701	10/03/2003	Keith B. Raskin	702.112.1	9858

37902 7590 02/16/2006

WRIGHT MEDICAL TECHNOLOGY, INC.
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EXAMINER	
RAMANA, ANURADHA	
ART UNIT	**PAPER NUMBER**
3733	

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/678,701	RASKIN ET AL.	
	Examiner	Art Unit	
	Anu Ramana	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6, 7 and 17 of copending Application No. 10/679,077 ('077) in view of Sorenson et al. (US 2002/0123723) and Reiley et al. (US 6,575,919).

Claim 6 of '077 discloses a method of delivering bone graft material to a bone defect area including the steps of: providing an instrument assembly having a bone graft needle that is an elongate tubular delivery member and an elongate penetrating member; inserting the elongate penetrating member into the lumen of the needle until the distal end of the elongate penetrating member extends from the distal end of the bone graft needle; removing the elongate penetrating member from the bone graft needle while retaining the distal end of the needle in the bone defect area; and

delivering a bone graft material in paste form via injection of the material through the bone graft needle wherein the bone graft material includes calcium sulfate.

Claim 6 of '077 discloses all elements of the claimed invention except for: a plurality of ports on the tubular delivery member; and injection of the bone graft material utilizing a syringe.

Sorensen et al. teach a tubular member used for directing liquid with a plurality of ports or "perforations" 85 wherein the ports can have an increasingly large diameter, breadth or length or may be increasingly less spaced apart as their location advances from the proximal to the distal end of the tubular element to more uniformly distribute a volume of treatment fluid to a larger area (Fig. 1 and paras [0033]-[0036]).

Reiley et al. teach using a syringe 136 to inject material through a cannula or "tubular member" 50 for precise control when filling a cavity or "bone defect" with material (Fig. 14, col. 10, lines 23-67 and col. 11, lines 1-10).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a plurality of ports on the tubular delivery member utilized in the method of claim 6 ('077), as taught by Sorensen et al., to uniformly distribute a volume of treatment fluid to a larger area, and a syringe, as taught by Reiley et al., to inject the material through the bone graft needle, in the method of Claim 6 ('077), for precise control when filling a cavity with material.

Regarding claims 11-17, the combination of claim 6 ('077), Sorensen et al. and Reiley et al. discloses the claimed invention except for the claimed distances of the ports from the proximal most edge of a distal end of the needle. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided ports at various distances from the proximal most part of the distal end of the bone graft needle, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claims 16 and 17, the combination of claim 7 ('077), Sorensen et al. and Reiley et al. discloses the claimed invention except for the needle having a J-type cannulated distal end and the claimed lengths. It would have been an obvious matter of

design choice to one skilled in the art at the time the invention was made to construct the needle with a J-type distal end, since applicant has not disclosed that this solves any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a distal end of a needle. *In re Dailey and Eilers, 149 USPQ 47 (1966).* Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided a needle with the claimed lengths, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley et al. (US 6,575,919) in view of Sorenson et al. (US 2002/0123723) and Kerr et al. (US 2003/0036762).

Reiley et al. disclose a method of delivering bone graft material to a bone defect area including the steps of: providing an instrument assembly 10 having a bone graft needle 50 that is an elongate tubular delivery member and a trocar or "an elongate penetrating member" 30; inserting the elongate penetrating member into the lumen of the needle until the distal end of the elongate penetrating member extends from the distal end of the bone graft needle; removing the elongate penetrating member from the bone graft needle while retaining the distal end of the needle in the bone defect area;

and delivering a material 138 in paste form via injection of the material through the bone graft needle utilizing a syringe (Figs. 2-4, 11, 14 and 16, col. 8, lines 57-67, col. 9, lines 1-17, col. 10, lines 23-67 and col. 11, lines 1-10).

Reiley et al. disclose all elements of the claimed invention except for: a plurality of ports on the tubular delivery member; and a bone graft material including calcium sulfate.

Sorensen et al. teach a tubular member used for directing liquid with a plurality of ports or "perforations" 85 wherein the ports can have an increasingly large diameter, breadth or length or may be increasingly less spaced apart as their location advances from the proximal to the distal end of the tubular element to more uniformly distribute a volume of treatment fluid to a larger area (Fig. 1 and paras [0033]-[0036]).

Kerr et al. teach a different types of bone treatment materials such as calcium sulfate, demineralized bone substitutes etc. (para [026]).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a plurality of ports on the tubular delivery member utilized in the method of Reiley et al., as taught by Sorensen et al., to uniformly distribute a volume of treatment fluid to a larger area. Further, it would have been obvious to have utilized a calcium sulfate material, as taught by Kerr et al., in the method of the combination of Reiley et al. and Sorensen et al., since it was well known to utilize this material as a bone filler.

Regarding claims 11-17, the combination of Reiley et al., Sorensen et al. and Kerr et al. discloses the claimed invention except for the claimed distances of the ports from the proximal most edge of a distal end of the needle and the claimed lengths of the tubular delivery member or bone graft needle. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided ports at various distances from the proximal most part of the distal end of the bone graft needle and to have provided a needle having the claimed lengths, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claims 16 and 17, the combination of Reiley et al., Sorensen et al. and Kerr et al. discloses the claimed invention except for the needle being made of stainless steel and having a J-type cannulated distal end. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the tubular delivery member or needle in the device of the combination of Reiley et al., Sorensen et al. and Kerr et al. of stainless steel, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Further, it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the needle with a J-type distal end, since applicant has not disclosed that this solves any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a distal end of a needle. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

The method steps of claims 3-18 are rendered obvious by the above discussion.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR Anuradha Ramana
February 8, 2006

EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER